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November 12, 1999

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Suitable Determination for Donors of Human Cellular and Tissue-Based Products
Docket No. 97N-484S

To Whom It May Concern:

I am the Director of Oocyte Donation at New York University Medical Center, and I am writing to you in response to your proposals concerning egg donation. Currently, egg donation is performed using fresh eggs, which are fertilized and transferred three to five days after the oocyte retrieval.

Quarantining embryos in a frozen state is a poor idea because cycles in which frozen embryos are utilized typically have a pregnancy rate that is one half that of fresh cycles. Pregnancy rates are very important couples undergoing oocyte donation because such a cycle is expensive, and most couples do not have the resources to make multiple attempts at the process. Pregnancy rates are also important because an oocyte donor is a very limited resource. A very small percentage of eligible women donate their eggs and many programs have over a year wait to receive eggs. An oocyte donation process that has a low pregnancy rate would result in a lower donor to pregnancy ratio, making the entire process at times futile.

If you could in any way demonstrate to me that freezing eggs would enhance the safety of the donation process I might be more apt to entertain your proposal. We currently perform most of the testing that you recommend twice, that last time being the week of the donation process. I am unaware of any infectious disease that has been transmitted from and egg donor to a recipient or resulting offspring anywhere in the world.

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I therefore recommend that the current method of oocyte donation continue. Strict screening methods must, of course, be the mainstay in providing safe and efficient patient care.

Sincerely,

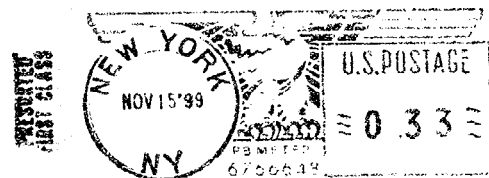
A handwritten signature in black ink, appearing to be 'FL' with a stylized flourish.

Frederick Licciardi, M.D.
NYU Medical Center
Director of Oocyte Donation
FL/cg



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